Challenges in the Use of Anthrax Vaccine Adsorbed (AVA) in the Pediatric Population as a Component of Post-Exposure Prophylaxis (PEP) A Report of the NBSB

Presented by:

NBSB Chair, John S. Parker, M.D., Major General (Retired)

- This presentation will briefly address the NBSB's deliberations, report, and final recommendation, at the request of the Presidential Commission for the Study of Bioethical Issues Chair, Dr. Amy Gutmann.

- Acknowledgement: The Report from the NBSB was completed due to the collaborative efforts of several subject matter experts and NBSB Board members, led by Drs. Daniel Fagbuyi and John Parker, Chair and Co-Chair of the Anthrax Vaccine Working Group.

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ASPR Charge to the Board on April 27, 2011:

"The NBSB has the expertise, experience, and demonstrated ability to deliberate on difficult issues such as these. Therefore, I would like the Board to consider particular issues around the use of Anthrax Vaccine Adsorbed (AVA), primarily in pediatric populations, but also considering other special populations who would not otherwise be covered under an Emergency Use Authorization (EUA), or under current product approved uses."

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Anthrax Vaccine Working Group Mission Statement:

Established under the National Biodefense Science Board (NBSB), the Anthrax Vaccine (AV) Working Group (WG) will investigate particular issues around the use of Anthrax Vaccine Adsorbed (AVA), in pediatric populations. The AV WG will identify and explore the risk and benefits of using AVA vaccine in pediatric populations, including risk communication, legal and ethical considerations, and challenges through the continuum of preparedness and response.

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Proposed Plan for PEP Following Exposure to *B. anthracis:*

In the event of the release of anthrax spores, the current USG plan is to ensure that AVA and antibiotics are made available to all children and adults following their actual or potential exposure to anthrax spores. Vaccination under these emergency conditions is entirely voluntary, and – for individuals under the age of 18 – would require informed consent from a parent or legal guardian under the current IND mechanism intended for providing AVA PEP to children.

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Questions debated by the NBSB :

1. What are the risks and benefits of attempting to perform an AVA vaccine safety and immunogenicity IND research protocol in children pre-event versus after an event?
2. What are the challenges for administering this vaccine under an Investigational New Drug (IND) after an event and how do these challenges compare with ethical considerations for attempting to gather sufficient data to permit use under an Emergency Use Authorization (EUA)?
3. What pre-planning should the U.S. government have in place to optimally perform an *investigational protocol post*-attack?
4. How should the U.S. government communicate these issues with parents, pediatricians, public health officials and political officials before and in response to an anthrax attack?

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Options Considered by the NBSB:

Option 1:

Conduct a pre-event research IND: The USG should develop and implement a pre-event, research IND to test the safety and immunogenicity of AVA in the pediatric population.

Option 2:

Do not conduct a pre-event study. Instead, conduct a post-event research IND: In the event of a public health emergency involving the release of *B. anthracis* bacteria or spores, the HHS plan is to follow current ACIP recommendations to administer AVA PEP and antibiotics to children, with parental permission, under a post-event, non-research IND.

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Final Recommendation – October 28, 2011:

The NBSB recommends **Option 1**, in light of the current HHS plan to follow the ACIP recommendations for the use of AVA for PEP following exposure to *B. anthracis spores:*

The issue should be referred to an appropriate review board to formally address the ethical considerations. This board should include ethicists and public representation. If the ethical considerations are adequately addressed, HHS should develop a plan for and conduct a pre-event study of AVA in children, to include a research IND. HHS should submit the study protocol to one or more IRBs, and comply with the 21 CFR 50.54 / 45 CFR 46.407 federal review process.

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THANK YOU

QUESTIONS?

The Report from the NBSB, *Challenges in the Use of Anthrax Vaccine Adsorbed (AVA) in the Pediatric Population as a Component of Post-Exposure Prophylaxis (PEP)*, is available at www.phe.gov/nbsb

For further questions, please email the NBSB mailbox: NBSB@HHS.GOV

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